K121771 (4/4)

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

NOV 7 2012

510(k) Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Kelli Anderson Project Manager, Regulatory Affairs Telephone: (574) 371-8087 Fax: (574) 372-4605
Date:	June 12, 2012
Trade Name:	*Zimmer® Persona*™ Personalized Knee System
Product Codes / Device:	MBH, OIY, JWH
Regulation Numbers / Description:	21 CFR § 888.3565 – Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR § 888.3560 – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive 21 CFR § 888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented
Predicate Device:	*Persona*™ Personalized Knee System (K113369, cleared March 27, 2012) *NexGen® Trabecular Metal*™ Metal Tibial Tray (K072160, cleared September 5, 2007) *Vivacit-E®* Vitamin E Highly Crosslinked Polyethylene Liners, manufactured by Zimmer, Inc. (K120370, cleared June 4, 2012) *E1*™ Antioxidant Infused Technology, Manufactured by Biomet Manufacturing Corp. (K100048, cleared March 9, 2010) DePuy Attune Knee System, manufactured by DePuy Orthopaedics, Inc. (K101433, cleared December 10, 2010)

Device Description:

The *Zimmer® Persona*™ Personalized Knee System is a semi-constrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial and patellar bones. The *Persona* Knee System utilizes a modular design between the tibial plates and articular surfaces.

Intended Use:

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

Porous coated tibial baseplate components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplates and all-polyethylene (UHMWPE and VEXLPE) patella components are indicated for cemented use only.

Comparison to Predicate Device:

The proposed *Zimmer® Persona*™ Personalized Knee System components are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Non-Clinical Performance and Conclusions:

Vivacit-E material characteristics for the *Persona* Knee System are identical to the predicate Zimmer *Vivacit-E* Acetabular Polyethylene Liners (K120370). In contrast to conventional polyethylene, the *Vivacit-E* material is delamination resistant and exhibits a reduction in wear according to knee simulator bench testing.

Bench testing outlined below was conducted according to FDA guidance documents:

Property or Characteristic	Test Results
Cantilever Fatigue Test of the *Persona Trabecular Metal* Tibia	Demonstrated adequate fatigue strength in the cantilever loading condition.
Wear Testing of *Persona* CR *Vivacit-E* UHMWPE Articular Surfaces Under Load and Motion Curves From the ISO 14243 Standard	Demonstrated that the wear characteristics of the *Persona* CR articular surfaces, when articulated against the *Persona* CR femoral component, are sufficient to survive expected *in vivo* loading conditions.
Wear Testing of *Persona* PS *Vivacit-E* UHMWPE Articular Surfaces Under Load and Motion Curves from the ISO 14243 Standard	Demonstrated that the wear characteristics of the *Persona* PS and UC articular surfaces, when articulated against a *Persona* femoral component, are sufficient to survive expected *in vivo* loading conditions.
Spine Fatigue Evaluation of the *Persona* PS *Vivacit-E* Articular Surfaces	Demonstrated that the spine of the *Persona* PS *Vivacit-E* articular surfaces has sufficient strength to survive expected *in vivo* stress/strain loading conditions.
Tibiofemoral Constraint Evaluation of the *Persona* CR/PS/UC *Vivacit-E* UHMWPE Articular Surface	Demonstrated that constraint values for the *Persona Vivacit-E* articular surfaces are comparable to data from the *Persona* Conventional UHMWPE articular surfaces. Therefore, the *Persona Vivacit-E* articular surfaces provide adequate constraint through the needed tibiofemoral flexion angles.
***Persona Vivacit-E* Patella Contact Area, Contact Pressure, and Constraint Evaluation**	Evaluated material properties of *Vivacit-E* and demonstrated that when mated with a *Persona* femoral component, it has sufficient mechanical strength to survive expected *in-vivo* loading conditions and provide adequate constraint.
Tibiofemoral Contact Area and Contact Pressure Evaluation of the *Persona* CR/UC/PS *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated that the contact area and contact pressure of the *Persona Vivacit-E* articular surfaces are comparable to data from previous testing on *Persona* Conventional UHMWPE articular surfaces.

Property or Characteristic	Test Results
Anterior Liftoff Testing of the *Persona Vivacit-E* Articular Surfaces	Demonstrated sufficient locking mechanism strength to survive potential worst case anterior liftoff loading conditions during deep flexion.
Posterior Liftoff Fatigue Strength of the *Persona Vivacit-E* Articular Surfaces	Demonstrated sufficient locking mechanism strength to survive potential worst case shear loading conditions.
Static Shear Strength of the *Persona* Tibia Locking Mechanism	Demonstrated adequate resistance of the modular articular surfaces to disassembly.
Modified Metallic Surface Characterization for the *Persona* Porous Two Peg Tibia Component with *Trabecular Metal*	Evaluated the *Trabecular Metal* material according to applicable mechanical, physical and chemical analyses listed in the guidance document.
Static Tensile, Static Shear and Shear Fatigue of *Trabecular Metal* Diffusion Bonded to Tivanium – One Hour Cycles	Demonstrated that one hour diffusion bonding cycles produces a bond that meets the 20 MPa static tensile test requirement.
Evaluation of Interactions of the Zimmer Legacy Knee and *Persona* Primary Implant Systems with the Magnetic Fields in the Magnetic Resonance Imaging (MRI) Environment	Demonstrated safety and compatibility within the MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 7 2012

Zimmer, Inc.
% Ms. Kelli J. Anderson
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K121771
Trade/Device Name: *Persona*™ Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY
Dated: September 21, 2012
Received: September 24, 2012

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Unknown~~ K121771

Device Name:

Persona™ Knee System

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121771